01-11-01 videotape/GAU 3305 3737

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Date of Mailing: January 9, 2001

Petitioner's Case No. 5050/296

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#36 1/18

In re Public Use Proceeding of:	Ted Christopher	Examiner:	F. Jaworski
Serial No.:	08/746,360	Group Art Unit:	3305
Filed:	November 8, 1996		
For:	Finite Amplitude Distortion-Based Inhomogeneous Pulse Echo Ultrasonic Imaging		

PETITIONER'S SUBMISSION OF SUPPLEMENTAL EVIDENCE IN RESPONSE TO APPLICANT'S OBJECTIONS

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to Applicant's Objections to the Admissibility of Petitioner's Evidence and in accordance with 37 C.F.R. § 1.292(a) and 37 C.F.R. §§ 1.671-1.685, Petitioner hereby submits:

1. Four evidentiary declarations as follows: (1) Second Evidentiary Declaration of Joan C. Main; (2) Third Evidentiary Declaration of Gregory L. Holley; (3) Second Evidentiary Declaration of John M. Sheldon; and (4) Second Evidentiary Declaration of Paul E. Chandler.

2. Nine exhibits as follows: (1) Betacam tape labeled "Copy of Betacam Tape With Time Codes Contrast Echocardiography Investigations"; (2) Frame 3:36:22; (3) Frame 3:49:20; (4) Frame 4:04:14; (5) Frame 5:24:04; (6) Frame 5:28:23; (7) Frame 5:36:05; (8) Frame 5:37:04; and (9) Frame 5:39:03.

The nine exhibits submitted herewith are identified as Petitioner Exhibit #12-#20. Additionally, as part of Petitioner's supplemental evidence in response to Applicant's Objections, Petitioner is relying on (1) a Betacam tape labeled "Contrast Echocardiography Investigations Loop Copy" and bearing a copyright notice "Copyright 1993 Asuson" and (2) a Betacam tape labeled "Copy of the Original Betacam Tape." These Betacam tapes are identified as Petitioner Exhibit #10 and #11, respectively. Petitioner Exhibit #10 and #11 are "things" under 37 C.F.R. § 1.672(b) and, accordingly, are not required to be filed or served with this submission. To provide Applicant with reasonable access to these exhibits per 37 C.F.R. § 1.672(b), Petitioner offers Applicant the opportunity to inspect and view Petitioner Exhibit #10 and #11 upon reasonable notice to Petitioner. Additionally, as a convenience to Applicant, Petitioner is filing and serving herewith a copy of Petitioner Exhibit #11. This copy is identified as Petitioner Exhibit #12.

Lastly, in accordance with 37 C.F.R. § 1.672(b) and (c), Petitioner submits the following Cumulative Index of Names of Witnesses and Cumulative Index of Exhibits. The declarations and exhibits associated with this Submission of Supplemental Evidence are identified by an asterisk (*).

CUMULATIVE INDEX OF NAMES OF WITNESSES

NAME OF WITNESS	NUMBER OF THE PAGE WHERE THE TESTIMONY OF THE WITNESS BEGINS
Joseph F. Hetz	Petitioner Page 1
Paul E. Chandler	Petitioner Page 3; * Petitioner Page 34
Sharon Mulvagh, M.D.	Petitioner Page 5
Joan C. Main	Petitioner Page 6; * Petitioner Page 14
Gregory L. Holley	Petitioner Page 8; * Petitioner Page 25
Janna G. Clark	Petitioner Page 12
John M. Sheldon	Petitioner Page 13; * Petitioner Page 32

CUMULATIVE INDEX OF EXHIBITS

EXHIBIT NUMBER	BRIEF DESCRIPTION OF NATURE OF EXHIBIT	NUMBER OF THE PAGE WHERE THE EXHIBIT IS FIRST IDENTIFIED AND OFFERED INTO EVIDENCE
Petitioner Exhibit #1	VHS videotape labeled "Copy of "Contrast Echocardiography Investigations Copy A""	Petitioner Page 1
Petitioner Exhibit #2	VHS videotape labeled "Copy of "Dr. Mulvahy Video II • Imaging""	Petitioner Page 1
Petitioner Exhibit #3	VHS videotape labeled "Copy of "Mayo Clinic #CSI, Echo Date 9-28-94, Complete Copy""	Petitioner Page 1
Petitioner Exhibit #4	Reprint of Journal Article: Ted Christopher, "Finite Amplitude Distortion-Based Inhomogeneous Pulse Echo Ultrasonic Imaging," IEEE UFFC Vol. 44(1) January 1997	Petitioner Page 4
Petitioner Exhibit #5	Frame A	Petitioner Page 10
Petitioner Exhibit #6	Frame B	Petitioner Page 10
Petitioner Exhibit #7	Frame C	Petitioner Page 10
Petitioner Exhibit #8	Frame D	Petitioner Page 10

Petitioner Exhibit #9	Frame E	Petitioner Page 10
* Petitioner Exhibit #10	Betacam tape labeled "Contrast Echocardiography Investigations Loop Copy" and bearing a copyright notice "Copyright 1993 Asuson"	Petitioner Page 17
* Petitioner Exhibit #11	Betacam tape labeled "Copy of the Original Betacam Tape"	Petitioner Page 18
* Petitioner Exhibit #12	Betacam tape labeled "Copy of Betacam Tape With Time Codes Contrast Echocardiography Investigations"	Petitioner Page 33
* Petitioner Exhibit #13	Frame 3:36:22	Petitioner Page 23
* Petitioner Exhibit #14	Frame 3:49:20	Petitioner Page 23
* Petitioner Exhibit #15	Frame 4:04:14	Petitioner Page 23
* Petitioner Exhibit #16	Frame 5:24:04	Petitioner Page 23
* Petitioner Exhibit #17	Frame 5:28:23	Petitioner Page 23
* Petitioner Exhibit #18	Frame 5:36:05	Petitioner Page 23
* Petitioner Exhibit #19	Frame 5:37:04	Petitioner Page 23
* Petitioner Exhibit #20	Frame 5:39:03	Petitioner Page 23

Dated: January 9, 2001

Respectfully submitted,

William A. Webb
Reg. No. 28,277
Attorney for Petitioner

BRINKS HOFER
GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610
(312) 321-4200

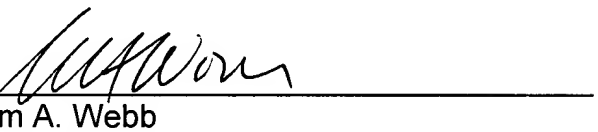
PROOF OF SERVICE

In accordance with 37 C.F.R. § 1.248, Petitioner hereby certifies that a duplicate copy of this paper and all supporting materials have been served on Applicant's attorney on January 9, 2001 via first class mail at the following address:

John S. Sensny, Esq.
Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, New York 11530-0299

Dated: January 9, 2001

Respectfully submitted,



William A. Webb
Reg. No. 28,277
Attorney for Petitioner

BRINKS HOFER
GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610
(312) 321-4200

#34

SECOND EVIDENTIARY DECLARATION OF JOAN C. MAIN

I, Joan C. Main, declare that the following facts are correct based on my personal knowledge:

1. I am federally licensed in invasive and non-invasive cardiology imaging modalities and have been practicing in this field for approximately 38 years. I have been employed in the marketing department at Acuson Corporation since May 1986. Over the last 12 years, I have been active in the area of contrast imaging with ultrasound. In connection with my responsibilities in this area, I have worked closely with physicians having a research interest in the field. I have conducted and recorded on videotape over 1,000 ultrasonic imaging studies with contrast, and many of these studies included harmonic imaging.

2. In approximately early 1993, I began working with an Acuson engineer, Paul Chandler, in supporting second harmonic engineering development efforts. Mr. Chandler told me that he made modifications to our Acuson 128 ultrasound system to support a second harmonic imaging mode. Mr. Chandler told me that, in the second harmonic imaging mode, the modified Acuson 128 ultrasound system transmits ultrasound energy at a fundamental center frequency of 2.5 MHz and selectively receives ultrasound echo signals at a second harmonic center frequency of 5.0 MHz while blocking ultrasonic echo signals at 2.5 MHz. Mr. Chandler told me that the modified Acuson 128

ultrasound system displays a 5.0 MHz icon when operating in second harmonic mode. The modified Acuson 128 ultrasound system is called "Serial Number 1122" at Acuson.

3. I have read the "Evidentiary Declaration of Paul E. Chandler" dated March 10, 1998 and believe that Serial Number 1122 described in paragraphs 2 and 3 of that declaration is the same Serial Number 1122 described in paragraph 2 above.

4. In approximately early 1993, Paul Chandler, Janna Clark (who is a clinical marketing specialist at Acuson), and I brought Serial Number 1122 to Dr. Tony DeMaria at the University of California at San Diego (UCSD) to conduct a proof of principle study to confirm that second harmonic signals generated by contrast agents could be imaged. At UCSD, under Dr. DeMaria's direction, we conducted a pig and a dog study using Serial Number 1122 with the Schering contrast agent called SSH508 (now known as Levovist®).

5. I have read the "Evidentiary Declaration of Janna G. Clark" dated March 10, 1998 and believe that the imaging described in paragraph 2 of that declaration is a reference to the proof of principle study described in paragraph 4 above.

6. In one study, which we called "Experiment 2," we imaged an apical 4-chamber view of a beating animal heart. While the beating animal heart was being imaged, I saw the 5.0 MHz icon displayed on Serial Number 1122. From the presence of this icon, I believe that Serial Number 1122 was operating in second harmonic mode.

7. Paul Chandler, Janna Clark, and I videotaped the beating animal heart while contrast agent was injected into the animal's vein. Videotaping ultrasound images is a standard technique for documenting ultrasound studies for later review, and reviewing videotaped ultrasound images is a standard technique reasonably relied upon by experts in the field of ultrasound imaging in forming opinions and inferences regarding the characteristics and features shown in the images.

8. During the initial frames, I saw the beating animal heart alone and did not see any indication of contrast agent present in the left ventricle of the beating animal heart. Contrast agent was traveling from the injection point and had not yet arrived in the left ventricle. Because I saw the 5.0 MHz icon displayed and because I did not see any indication of contrast agent present in the image of the left ventricle, the image of the left ventricle was generated at the second harmonic frequency in the absence of contrast agent.

9. After the initial frames, I saw the first puff of contrast agent in the left ventricle.

10. Also in Experiment 2, we imaged and videotaped an apical 4-chamber view of the beating animal heart with Serial Number 1122 operating in standard or fundamental mode while contrast agent was injected into the animal's vein. During the initial frames, I saw the beating animal heart alone and did not see any indication of contrast agent present in the left ventricle of the beating animal heart. Contrast agent was traveling from the injection point and had not yet arrived in the left ventricle. During this imaging, I did not see

the 5.0 MHz icon displayed on Serial Number 1122. Because I did not see the 5.0 MHz icon displayed and because I did not see any indication of contrast agent present in the image of the left ventricle, the image of the left ventricle was generated with Serial Number 1122 operating in standard or fundamental mode in the absence of contrast agent.

11. After the initial frames, I saw the first puff of contrast agent in the left ventricle.

12. Segments of the videotaped images from Experiment 2 were documented on a Betacam tape titled "Contrast Echocardiography Investigations Loop Copy." The Betacam tape bears a copyright notice on the label (with Acuson's name mis-spelled) as follows: "Copyright 1993 Asuson." I will refer to this tape as "the original Betacam tape." As indicated by the phrase "loop copy," segments of the videotaped images from Experiment 2 were recorded several times on the original Betacam tape to allow the segments to be repeatedly shown during a single play of the original Betacam tape.

13. In June of 1993, I personally presented the original Betacam tape on the show floor at the American Society of Echocardiography. This was a public showing in that no non-disclosure agreements were signed or requested. The American Society of Echocardiography is the governing body of echocardiography in the United States and is a well-established forum for scientists, physicians, and other practitioners to share echocardiography information. Because the original Betacam tape was a loop copy, segments of

the videotaped images from Experiment 2 were repeatedly shown as the original Betacam tape played.

14. I sought out and presented the original Betacam tape for viewing by approximately 70 key investigators on the show floor of the American Society of Echocardiography. Key investigators are thought leaders in echocardiography and are the people who would be the most interested in learning of new advances in echocardiography. I encouraged the key investigators to ask questions and to use the information presented on the original Betacam tape in their own practices.

15. On January 4, 2001, I reviewed a Betacam tape titled "Contrast Echocardiography Investigations Loop Copy." The Betacam tape bears a copyright notice on the label (with Acuson's name mis-spelled) as follows: "Copyright 1993 Asuson." Based on my review, I believe the tape to be the original Betacam tape described in paragraphs 12-14 above. I do not observe any indication that the original Betacam tape has been altered since I presented it at the American Society of Echocardiography in June of 1993, and I believe the tape is unchanged.

16. The original Betacam tape does not include time code numbers. To provide a reference by which to identify portions of the videotaped images, Greg Holley and I asked the Supervisor of Visual Communications at Acuson, John Sheldon, to copy one of the loop segments of the original Betacam tape onto a Betacam tape having time code numbers. I will refer to this copy as "the copy of the original Betacam tape." I reviewed the copy of the original Betacam

tape and believe it to be an accurate copy of the corresponding loop segment of the original Betacam tape. The copy of the original Betacam tape is labeled "Copy of the Original Betacam Tape" and is signed and dated by John Sheldon.

17. At time code 3:36:22 of the copy of the original Betacam tape, I observe an image shown with two legends: one to the left of and one below the image. I observe the legend to the left of the image to read "Backscatter from tissue occurs at the transmitted frequency" and the legend below the image to read "2.5 MHz." These legends confirm my understanding that Serial Number 1122 was transmitting ultrasound energy at a fundamental center frequency of 2.5 MHz.

18. At time code 3:49:20, I observe another image shown with two legends: one to the left of and one below the image. I observe the legend to the left of the image to read "Backscatter from bubbles can occur at multiples of the transmitted frequency" and the legend below the image to read "5.0 MHz." At time code 4:04:14, I observe a new legend to the left of the image, which reads "The second multiple is commonly referred to as the second harmonic." These legends confirm my understanding that, when operating in second harmonic mode, Serial Number 1122 receives ultrasound echoes at a second harmonic center frequency of 5.0 MHz.

19. At time code 5:24:04, I observe two images with the legend "Experiment 2: Tissue Signal Level Constant" displayed above the images. The left-hand image is displayed above the legend "Standard with Contrast," and the right-hand image is displayed above the legend "Second Harmonic with

Contrast." I recognize the right-hand image as the image recorded during the study described in paragraphs 6-9 above and the left-hand image as the image recorded during the study described in paragraphs 10-11 above. These legends confirm my understanding that the left-hand image was generated with Serial Number 1122 operating in standard or fundamental mode and that the right-hand image was generated with Serial Number 1122 operating in second harmonic mode. The legend "with Contrast" refers to the final condition of the experiment and was not meant to convey that contrast agent was present in every image frame shown during this segment.

20. I recognize the images shown from time code 5:36:05 to time code 5:39:03 in the right-hand image as being the images generated after contrast agent was injected into the animal but before the contrast agent arrived in the left ventricle. In this segment, I see the beating animal heart alone and do not see any indication of contrast agent in the left ventricle. I recognize these images to be those images generated during the portion of Experiment 2 described in paragraph 8 above.

21. At time code 5:39:03, I see the first puff of contrast agent in the left ventricle in the right-hand image. The image frames shown in the moving clip of the right-hand image after 5:39:03 are images generated after contrast agent arrived in the left ventricle. I recognize these images to be those images generated during the portion of Experiment 2 after the arrival of contrast agent described in paragraph 9 above.

22. I recognize the images shown from time code 5:24:04 to time code 5:28:23 in the left-hand image as being the images generated after contrast agent was injected into the animal but before the contrast agent arrived in the left ventricle. In this segment, I see the beating animal heart alone and do not see any indication of contrast agent in the left ventricle. I recognize these images to be those images generated during the portion of Experiment 2 described in paragraph 10 above.

23. At time code 5:28:23, I see the first puff of contrast agent in the left ventricle in the left-hand image. The image frames shown in the moving clip of the left-hand image after 5:28:23 are images generated after contrast agent arrived in the left ventricle. I recognize these images to be those images generated during the portion of Experiment 2 after the arrival of contrast agent described in paragraph 11 above.

24. The images shown from time code 5:36:05 to time code 5:39:03 in the right-hand image include a visually-perceptible component that was formed from the second harmonic response of biological tissue as a result of finite amplitude distortion during the propagation of the ultrasound wave through the animal. I will use the term "Tissue Harmonic Image" in this declaration to refer to an image that includes such a visually-perceptible component.

25. I compared the edge definition at the apex of the heart and at the right-hand lateral portion of the left-ventricle wall in the left-hand and right-hand images before the arrival of contrast agent in the left ventricle (from time code 5:24:04 to time code 5:28:23 in the left-hand image and from time code 5:36:05

to time code 5:39:03 in the right-hand image). From this comparison, I observed that the right-hand image has improved clarity in the edge definition at the apex of the heart and at the right-hand lateral portion of the left-ventricle wall. These improvements in tissue definition in the right-hand image are characteristics of a Tissue Harmonic Image.

26. I compared the dot size and the amount of penetration in the left-hand and right-hand images before the arrival of contrast agent in the left ventricle (from time code 5:24:04 to time code 5:28:23 in the left-hand image and from time code 5:36:05 to time code 5:39:03 in the right-hand image). I observed a larger dot size in the right-hand image than in the left-hand image. This difference indicates that the right-hand image was generated using a higher frequency than the frequency used to generate the left-hand image. I also observed similar penetration depth in the right-hand and left-hand images. Based on these observations, it is my opinion that the image shown from time code 5:36:05 to time code 5:39:03 in the right-hand image is a Tissue Harmonic Image and not a fundamental image.

27. I compared brightness of the contrast agent in the left-hand and right-hand images in the image clip starting at time code 5:28:23 in the left-hand image and in the image clip starting at time code 5:39:03 in the right-hand image. I observed that the contrast agent is brighter in the right-hand image than it is in the left-hand image. The appearance of brighter contrast agent is a characteristic of a harmonic image. This observation corroborates my opinion that the image shown in the right-hand image before the arrival of contrast

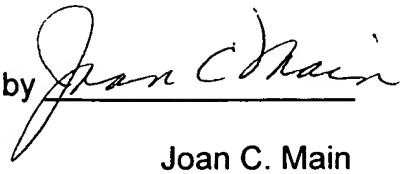
agent in the left ventricle (from time code 5:36:05 to time code 5:39:03) is a Tissue Harmonic Image.

28. Comparing clarity in the edge definition at the apex of the heart and at the right-hand lateral portion of the left-ventricle wall and comparing dot size, penetration depth, and contrast agent brightness are reliable principles and methods for determining whether an image is a Tissue Harmonic Image. I reliably applied these principles and methods to the images that I observed in forming my opinion. Further, my opinion is based upon sufficient facts and data of the type reasonably relied upon by experts in the field of ultrasound imaging in forming opinions and inferences regarding the characteristics and features shown in ultrasound images.

29. The moving clips in the left-hand and right-hand images described above are repeated in the copy of the original Betacam tape. The observations made with respect to the left-hand and right-hand images described above apply equally to the repeat showing of the clips.

30. Today, I reviewed a set of image frames from John Sheldon. These image frames are labeled with the following time code numbers: 3:36:22, 3:49:20, 4:04:14, 5:24:04, 5:28:23, 5:36:05, 5:37:04, and 5:39:03. These image frames are accurate copies of the images shown in the indicated time codes of the copy of the original Betacam tape. These image frames accompany this declaration.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Dated this 8th day of January, 2001, by 

Joan C. Main

#34

THIRD EVIDENTIARY DECLARATION OF GREGORY L. HOLLEY

I, Gregory L. Holley, declare that the following facts are correct based on my personal knowledge:

1. I received a bachelors degree in electrical engineering and a masters degree in electrical engineering with an optics and imaging specialty from Stanford University. I am an Image Analysis Engineer at Acuson Corporation and have held this position since July 20, 1987. I have been involved in the development of second harmonic imaging at Acuson for the last several years. My involvement, which began between December 1995 and October 1996, has included the analysis of second harmonic images and their characteristics. I have reviewed recorded images from approximately 15 contrast image studies. At least 3 of these contrast image studies were recorded on videotape.

2. On January 4, 2001, I reviewed a Betacam tape titled "Contrast Echocardiography Investigations Loop Copy." The Betacam tape bears a copyright notice on the label (with Acuson's name mis-spelled) as follows: "Copyright 1993 Asuson." I will refer to this tape as "the original Betacam tape."

3. Videotaping ultrasound images is a standard technique for documenting ultrasound studies for later review, and reviewing videotaped ultrasound images is a standard technique reasonably relied upon by experts in the field of ultrasound imaging in forming opinions and inferences regarding the characteristics and features shown in the images.

4. The original Betacam tape does not include time code numbers. To provide a reference by which to identify portions of the videotaped images, Joan Main and I asked the Supervisor of Visual Communications at Acuson, John Sheldon, to copy one of the loop segments of the original Betacam tape onto a Betacam tape having time code numbers. I will refer to this copy as "the copy of the original Betacam tape." I reviewed the copy of the original Betacam tape and believe it to be an accurate copy of the corresponding loop segment of the original Betacam tape. The copy of the original Betacam tape is labeled "Copy of the Original Betacam Tape" and is signed and dated by John Sheldon.

5. At time code 3:36:22 of the copy of the original Betacam tape, I observe an image shown with two legends: one to the left of and one below the image. I observe the legend to the left of the image to read "Backscatter from tissue occurs at the transmitted frequency" and the legend below the image to read "2.5 MHz." In my opinion, these legends teach that the ultrasound system used to generate the images shown in the original Betacam tape was transmitting ultrasound energy at a fundamental center frequency of 2.5 MHz. Paragraphs 2 and 17 of the "Second Evidentiary Declaration of Joan C. Main" corroborate my opinion.

6. At time code 3:49:20, I observe another image shown with two legends: one to the left of and one below the image. I observe the legend to the left of the image to read "Backscatter from bubbles can occur at multiples of the transmitted frequency" and the legend below the image to read "5.0 MHz." At time code 4:04:14, I observe a new legend to the left of the image, which reads

"The second multiple is commonly referred to as the second harmonic." In my opinion, these legends teach that the ultrasound system generating images labeled as second harmonic images was receiving ultrasound echoes at a second harmonic center frequency of 5.0 MHz. Paragraphs 2 and 18 of the "Second Evidentiary Declaration of Joan C. Main" corroborate my opinion.

7. From the legends described in paragraphs 5 and 6 above, I conclude that images shown in the copy of the original Betacam tape having the legend "second harmonic" were generated with an ultrasound system transmitting ultrasound energy at a fundamental center frequency of 2.5 MHz and selectively receiving ultrasonic harmonic signals at a second harmonic center frequency of 5.0 MHz. I also conclude that images having the legend "fundamental" or "standard" were generated with an ultrasound system transmitting ultrasound energy at a fundamental center frequency of 2.5 MHz and receiving ultrasound echoes at the same fundamental center frequency of 2.5 MHz. Paragraphs 17 and 18 of the "Second Evidentiary Declaration of Joan C. Main" corroborate my opinion.

8. At time code 5:24:04, I observe two images with the legend "Experiment 2: Tissue Signal Level Constant" displayed above the images. The left-hand image is displayed above the legend "Standard with Contrast," and the right-hand image is displayed above the legend "Second Harmonic with Contrast." I recognize the left-hand and right-hand images as ultrasound images of a beating animal heart.

9. Based on paragraph 19 of the "Second Evidentiary Declaration of Joan C. Main," I understand that the legend "with Contrast" refers to the final condition of the experiment and was not meant to convey that contrast agent was present in every image frame.

10. From time code 5:36:05 to time code 5:39:03 in the right-hand image and from time code 5:24:04 to time code 5:28:23 in the left-hand image, I see the beating animal heart alone and do not see any indication of contrast agent in the left ventricle. I understand from paragraphs 8, 10, 20, and 22 of the "Second Evidentiary Declaration of Joan C. Main" that these images were taken after contrast agent was injected into the animal but before the contrast agent arrived in the left ventricle.

11. At time code 5:39:03 in the right-hand image, I see the first puff of contrast agent in the left ventricle. At time code 5:28:23 in the left-hand image, I see the first puff of contrast agent in the left ventricle. It is my opinion that the images shown in the moving clip of the left-hand image after time code 5:28:23 and in the moving clip of the right-hand image after time code 5:39:03 were generated after contrast agent arrived in the left ventricle. Paragraphs 21 and 23 of the "Second Evidentiary Declaration of Joan C. Main" corroborate my opinion.

12. I have reviewed the paper by Ted Christopher titled, "Finite Amplitude Distortion-Based Inhomogeneous Pulse Echo Ultrasonic Imaging," (IEEE Trans. USFC 44(1) (Jan. 97) pp. 125-139). It is my understanding that finite amplitude distortion during propagation of an ultrasound wave through the

body, as described in Christopher's paper, is the mechanism by which the second harmonic response of tissue is generated.

13. The images shown from time code 5:36:05 to time code 5:39:03 in the right-hand image include a visually-perceptible component that was formed from the second harmonic response of biological tissue as a result of finite amplitude distortion during the propagation of the ultrasound wave through the animal. I will use the term "Tissue Harmonic Image" in this declaration to refer to an image that includes such a visually-perceptible component.

14. I compared the edge definition at the apex of the heart and at the right-hand lateral portion of the left-ventricle wall in the left-hand and right-hand images before the arrival of contrast agent in the left ventricle (from time code 5:24:04 to time code 5:28:23 in the left-hand image and from time code 5:36:05 to time code 5:39:03 in the right-hand image). From this comparison, I observed that the right-hand image has improved clarity in the edge definition at the apex of the heart and at the right-hand lateral portion of the left-ventricle wall. This is shown, for example, in the portion of the copy of the original Betacam tape around 5:37:04. These improvements in tissue definition in the right-hand image are characteristics of a Tissue Harmonic Image.

15. I compared brightness of the contrast agent in the left-hand and right-hand images in the image clip starting at time code 5:28:23 in the left-hand image and in the image clip starting at time code 5:39:03 in the right-hand image. I observed that the contrast agent is brighter in the right-hand image than it is in the left-hand image. The appearance of brighter contrast agent is a

characteristic of a harmonic image. This observation corroborates my opinion that the image shown in the right-hand image before the arrival of contrast agent in the left ventricle (from time code 5:36:05 to time code 5:39:03) is a Tissue Harmonic Image.

16. Comparing clarity in the edge definition at the apex of the heart and at the right-hand lateral portion of the left-ventricle wall and comparing contrast agent brightness are reliable principles and methods for determining whether an image is a Tissue Harmonic Image. I reliably applied these principles and methods to the images that I observed in forming my opinion. Further, my opinion is based upon sufficient facts and data of the type reasonably relied upon by experts in the field of ultrasound imaging in forming opinions and inferences regarding the characteristics and features shown in ultrasound images.

17. The moving clips in the left-hand and right-hand images described above are repeated in the copy of the original Betacam tape. The observations made with respect to the left-hand and right-hand images described above apply equally to the repeat showing of the clips.

18. On January 4, 2001, I asked John Sheldon to generate hard copies of the images shown at the following time codes of the copy of the original Betacam tape: 3:36:22, 3:49:20, 4:04:14, 5:24:04, 5:28:23, 5:36:05, 5:37:04, and 5:39:03.

19. Today, I reviewed a set of image frames from John Sheldon. These image frames are labeled with the following time code numbers: 3:36:22,

3:49:20, 4:04:14, 5:24:04, 5:28:23, 5:36:05, 5:37:04, and 5:39:03. These image frames are accurate copies of the images shown in the indicated time codes of the copy of the original Betacam tape. These image frames accompany this declaration.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Dated this 8th day of January, 2001, by Gregory L Holley

Gregory L. Holley

SECOND EVIDENTIARY DECLARATION OF JOHN M. SHELDON

I, John M. Sheldon, declare that the following facts are correct based on my personal knowledge:

1. I am Supervisor of Visual Communications at Acuson and have worked for Acuson since 1989 as a photo/video technician. I have approximately 20 years of experience in the photo/video industry.

2. I designed a workstation that is relied on at Acuson for digitizing and generating accurate hard copies of images from videotapes. I have personally digitized and generated hard copies of over 5,000 images from Betacam tapes, and many of those hard copies were generated with this workstation.

3. On January 4, 2001, Greg Holley and Joan Main gave me a Betacam tape titled "Contrast Echocardiography Investigations Loop Copy." The Betacam tape bears a copyright notice on the label (with Acuson's name mis-spelled) as follows: "Copyright 1993 Asuson." I will refer to this tape as "the original Betacam tape." Mr. Holley and Ms. Main asked me to copy one of the loop segments of the original Betacam tape onto a Betacam tape having time code numbers. I will refer to this copy as "the copy of the original Betacam tape." I reviewed the copy of the original Betacam tape and believe it to be an accurate copy of the corresponding loop segment of the original Betacam tape. I labeled this copy "Copy of the Original Betacam Tape" and signed and dated the label.

4. On January 4, 2001, Mr. Holley asked me to generate hard copies of the images shown at the following time codes of the copy of the original Betacam tape: 3:36:22, 3:49:20, 4:04:14, 5:24:04, 5:28:23, 5:36:05, 5:37:04, and 5:39:03.

5. Using the workstation described in paragraph 2 above, I generated 10 sets of image frames of the images shown on the copy of the original Betacam tape at the time codes listed in paragraph 4 above. On each image frame, I placed a label listing the time code associated with the image.

6. I compared the image frames of paragraph 5 and the copy of the original Betacam tape, and the image frames are accurate hard copies of the corresponding portions of the copy of the original Betacam tape.

7. I gave Mr. Holley and Ms. Main a set of image frames of paragraph 5.

8. I made 6 copies of the copy of the original Betacam tape. I reviewed these copies and believe them to be accurate copies of the copy of the original Betacam tape. I labeled each of the 6 copies "Copy of Betacam Tape With Time Codes Contrast Echocardiography Investigations" and numbered and dated the labels.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Dated this 9th day of January, 2001 by

John M. Sheldon

SECOND EVIDENTIARY DECLARATION OF PAUL E. CHANDLER

I, Paul E. Chandler, declare that the following facts are correct based on my personal knowledge:

1. I received bachelor's degree in biology from the University of California at Los Angeles, and a master's and Ph.D. degrees in Radiological Sciences from the University of California at Irvine. My Ph.D. studies were concentrated within the medical ultrasound sciences. I was employed by Acuson as a Member of the Technical Staff from December 1986 to July 1994. I was a consultant to Acuson from May 1995 to November 1997. From July 1994 to May 1995, I was neither employed by nor consulting for Acuson due to a disability. From approximately 1991 to approximately 1997, a significant portion of my efforts was directed to my interest in the interplay between ultrasound systems and contrast agents. I am currently a Systems Engineer/Project Manager at SPAWAR Systems Center in San Diego, California.

2. In approximately 1992 at the suggestion of Reinhard Schlief, I modified an Acuson 128 ultrasound system to support second harmonic imaging. This involved specifying the correct frequency pair to cause the system to transmit ultrasound energy at 2.5 MHz and to receive ultrasound echo signals at 5.0 MHz while blocking ultrasonic echo signals at 2.5 MHz. To this end, I arranged to have the modification burned into a Programmable Array Logic (PAL) device on one of the boards, and I arranged to have the system

software modified. I also procured a prototype wide band transducer from Acuson's Principal Fellow, Amin Hanafy. The whole process took a couple of days to complete.

3. The first system is called "Serial Number 1122" at Acuson. Subsequently, I instructed Art Tofanelli in how to modify other Acuson systems. In the next few years, pursuant to my requests and requests of others at Acuson, 8 additional systems were built in this manner. All of these systems highlight a 5.0 MHz icon on the screen when transmitting ultrasound energy at a fundamental center frequency of 2.5 MHz and receiving ultrasound echo signals at the second harmonic frequency of 5.0 MHz.

4. I conducted conventional electronic tests on Serial Number 1122 and confirmed that Serial Number 1122 selectively transmitted ultrasound energy at a fundamental center frequency of 2.5 MHz and selectively received ultrasound echo signals at a second harmonic center frequency of 5.0 MHz while blocking ultrasonic signals at 2.5 MHz. These conventional electronic tests are based on reliable principles and methods for determining the frequency at which an ultrasound system is transmitting and receiving ultrasound energy. I reliably applied these principles and methods to Serial Number 1122 in forming my opinion. Further, my opinion is based upon sufficient facts and data of the type reasonably relied upon by experts in the field of ultrasound imaging in forming opinions and inferences regarding the frequency at which an ultrasound system is transmitting and receiving ultrasound energy.

5. In approximately early 1993, I told Joan Main that, in the second harmonic imaging mode, Serial Number 1122 transmits ultrasound energy at a fundamental center frequency of 2.5 MHz and selectively receives ultrasound echo signals at a second harmonic center frequency of 5.0 MHz while blocking ultrasonic echo signals at 2.5 MHz. I told Ms. Main that Serial Number 1122 displays a 5.0 MHz icon when operating in second harmonic mode.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Dated this 8th of January, 2001 by

Paul E. Chandler